

**Amendment and Response**

Applicant: Michael F. Hoey et al.

Serial No.: 10/699,548

Filed: October 31, 2003

Docket No.: M190.133.102

Title: APPARATUS AND METHOD FOR CREATING, MAINTAINING, AND CONTROLLING A VIRTUAL ELECTRODE USED FOR THE ABLATION OF TISSUE

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**REMARKS**

This is responsive to the Non-Final Office Action mailed April 24, 2006. In that Office Action, the Examiner rejected claims 6-16, 19-32, 35-45, and 48 under 35 U.S.C. § 103(a) as being unpatentable over Jackson et al., U.S. Patent No. 5,383,874 ("Jackson") in view of Osadchy et al., U.S. Patent No. 6,266,551. Claims 17, 18, 33, 34, 46, and 47 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jackson and Osadchy, and further in view of Nardella, U.S. Patent No. 5,334,193 ("Nardella").

With this Response, claims 6, 10, 11, 20, 22, 24, 26, 36, 38, and 39 have been amended. Claims 6-48 remain pending in the application and are presented for reconsideration and allowance.

**Support for Amendments**

Support for the amendment of claims 6, 20, and 36 is found throughout the Specification, for example at page 39, line 22 to page 40, line 26 and page 46, lines 1-7 (describing a predetermined period of time between power level increases or decreases); page 30, lines 4-14 (describing that a temperature control loop will modulate RF power such that a temperature is maintained for a predetermined period of time); page 32, lines 16-28 (describing that fluid flow rates should be maintained for a predetermined period of time before decreasing flow rate due to a subsequent impedance measurement); and page 24, lines 19-24 (describing an interval timer activated to prevent beginning the application of radio frequency power to a patient until a predetermined time period has expired, allowing the generator to cool and to prevent continuous, uninterrupted application of power to a patient).

Support for the amendment of claims 10, 24, and 39 can be found throughout the Specification, for example at page 24, lines 19-24 (describing an interval timer activated to prevent beginning anew the application of radio frequency power to a patient until a predetermined time period has expired, allowing the generator to cool and to prevent continuous, uninterrupted application of power to a patient).

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### **35 U.S.C. § 103 Rejections**

As a preliminary matter, Osadchy is used in support of all of the above-referenced grounds for rejection. However, the Osadchy reference cited by the Examiner is only properly afforded a 35 U.S.C. § 102(e) priority date as of February 17, 1999. *See* MPEP 706.02(f)(1). As the instant application claims a priority date at least as of July 7, 1998 via U.S. Provisional App. Ser. No. 60/091,959, Osadchy is not a proper § 102(e) reference. Additionally, as the cited Osadchy reference does not qualify as prior art under any other applicable section of 35 U.S.C. § 102, it is believed that the Examiner's grounds of rejection are fully traversed. For at least such reasons, the rejection of claims 6-48 should be withdrawn. Furthermore, the rejection of claims 6-48 are patentably distinct from the cited references for at least the additional reasons presented below.

Claim 6 as amended relates, in part, to a processor for receiving predetermined time limit information for at least one operating parameter and increasing a value of the at least one operating parameter after the predetermined time limit has elapsed. Claim 6 is rejected as unpatentable over Jackson in view of Osadchy. The Examiner has agreed that Jackson does not disclose that time limit information is used as an operating parameter stored on a memory chip. NFOA at p. 3. Instead, the Office Action cites Osadchy against claim 6. *Id.* For at least the reasons described below, Osadchy fails to teach or suggest the limitations of claim 6 as amended, and, in fact, teaches away from such limitations.

As referenced by the Examiner, Osadchy describes tracking the number of times a catheter has been used and/or the duration of use by keeping a record corresponding to the number of times and/or the length of time that the catheter may be used. Once the time/number of uses expires, a user is given a message indicating that the catheter is unsuitable for further use. *Osadchy* at col. 6, ll. 45-65; col. 8, ll. 12-20. In the words of Osadchy, the catheter system keeps a record of an expiration time "after which the catheter may not be used." *Id.* at col. 6, ll. 4-6 (emphasis added).

In direct contrast, claim 6 addresses increasing a value of at least one operating parameter after a predetermined time limit has elapsed. In other words, while Osadchy teaches reducing operation of the catheter system to zero, i.e., preventing use of the catheter system, claim 6

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recites increasing a particular operating parameter of a surgical instrument. Thus, Odachy fails to teach or suggest the limitations of claim 6 as amended. Indeed, because Osadchy teaches completely stopping use of the catheter system upon reaching a predetermined time, Osadchy teaches away from increasing a value of at least one operating parameter of a surgical instrument as required by claim 6. None of the other cited references teach or suggest such limitations - as referenced by the Examiner, Jackson fails to disclose that time limit information is used as an operating parameter stored on a memory chip and, though not cited, following a good faith review, it is believed that Nardella is also unavailing in this respect.

In sum, a *prima facie* case of obviousness has not been established for claim 6 as amended. As such, withdrawal of the rejection of claim 6, allowance of claim 6 and claims 7-19 depending therefrom, and notice to that effect are respectfully requested.

Claim 20 as amended can be similarly distinguished from the cited references. Claim 20 as amended relates, in part, to identifying means programmed to provide at least one predetermined time limit designating an elapsed time required prior to changing an identifying characteristic of a surgical instrument to a non-zero value. As referenced above in association with claim 6, Osadchy teaches reducing operation of the catheter system to zero, i.e., preventing use of the catheter system, or "turning it off." Thus, the limitations of claim 20 relating to a predetermined time limit designating an elapsed time required prior to changing an identifying characteristic of a surgical instrument to a non-zero value are not taught or suggested by Osadchy. Once again, due to the direct contrast between the limitations of claim 20 and the disclosure of Osadchy, one having ordinary skill in the art would be taught away from the limitations of claim 20 by Osadchy. As Jackson and Nardella are similarly believed unavailing with respect to such limitations, claim 20 as amended is patentable over the cited references.

In sum, a *prima facie* case of obviousness has not been established for claim 20 as amended. As such, withdrawal of the rejection of claim 20, allowance of claim 20 and claims 20-35 depending therefrom, and notice to that effect are respectfully requested.

Claim 36 as amended relates, in part, changing a value of an operating parameter following elapse of a predetermined time limit and ablating tissue with ablating energy delivered from an RF generator through a surgical instrument to tissue to be ablated following elapse of the

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predetermined time limit based upon a changed value of the operating parameter. Similarly to the claims 6 and 20 as amended, claim 36 is at odds with the teachings of Osadchy. In particular, Osadchy describes “turning off” a catheter system upon expiration of a time limit. In direct contrast, claim 36 relates to changing an operating parameter and, after a predetermined time limit, continuing to ablate tissue. Thus, the cited references fail to teach or suggest the limitations of claim 36 and, in fact, teach away from such limitations.

In sum, a *prima facie* case of obviousness has not been established for claim 36 as amended. As such, withdrawal of the rejection of claim 36, allowance of claim 36 and claims 37-48 depending therefrom, and notice to that effect are respectfully requested.

The dependent claims can be further distinguished from the cited references for at least the following additional reasons. For example, in general terms, each of dependent claims 10, 24 and 39 relate to a predetermined time limit which must expire before a surgical instrument may be used to deliver ablating energy. In direct contrast, Osadchy relates to stopping operation of a catheter system after expiration of a particular time. Thus, Osadchy expressly teaches away from the limitations of claims 10, 24, and 39. For at least such additional reasons, claims 10, 24, and 39 should be deemed allowable.

In sum, according to at least the clarifications presented above, claims 6-48 are patentable over the cited references. As such, it is respectfully requested that the rejection of those claims be withdrawn, that they be allowed, and that notice to that effect be provided.

#### **CONCLUSION**

In view of the above, Applicant respectfully submits that pending claims 6-48 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 6-48 are respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

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Any inquiries may be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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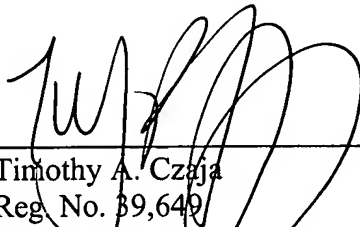
Respectfully submitted,

Michael F. Hoey et al.,

By their attorneys,

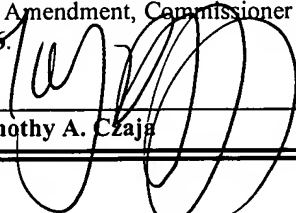
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**CERTIFICATE UNDER 37 C.F.R. 1.8:**

The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope address to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 27th day of July, 2006.

By:   
Name: Timothy A. Czaja